UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS	

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF
TRACK 1 DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT

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I. PLAINTIFFS' CONSTRUCTION OF "AWP" IS INCORRECT

Plaintiffs now deny ever having asserted that AWP must equal ASP as a matter of law. (*See* Plaintiffs' Memorandum in Opposition to Track 1 Defendants' Joint Motion for Summary Judgment ("Pls.' Opp'n") at 1 ("[T]his case is not about AWP being equal to ASP.") To the contrary, Plaintiffs have repeatedly asserted, and their theory of liability has been based upon convincing the Court, that AWP must equal ASP "by statute." Indeed, they instructed their expert, Dr. Hartman, to build his damages case on that assumption. For example:

- In his class certification report, Dr. Hartman states: "For Medicare Part B physician administered drugs, AWP $^{\text{but for}}$ = AAC = ASP by regulation."[1] As Dr. Hartman explained, "but for spreads" are "spreads whose AWP and ASP are unaffected by the AWP scheme and fraud."[2]

- He testified at his deposition that, under the Medicare Part B regulations from 1992 through 1997, "the markup above ASP was zero, that is the but-for markup. In other words, the but-for AWP equals the ASP."[3]

- In his merits expert report, Dr. Hartman is even more explicit, stating: "by statute the but-for spread for those single-source brand-named drugs reimbursed by Sub-Classes 1 and 2 was 0.0%," and for multi-source drugs "the ASP was the 'but-for AWP' for 1991-2003, and the 'but-for spread' was 0.0%."[4] Although in this report, Dr. Hartman used the "zero by statute" spread to calculate Class 1 and Class 2 damages only, on February 3, 2006, Dr. Hartman filed a "supplemental" report, at counsel's direction,

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[1] Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification dated Sept. 3, 2004, ¶ 30(e), annexed to the Declaration of Jessica V. Barnett submitted herewith ("Barnett Decl.") Ex. 1. *See also id.* ¶ 33 (Barnett Decl. Ex. 1).

[2] *Id.* ¶ 20 (Barnett Decl. Ex. 1).

[3] Hartman Dep. Tr. (Oct. 8, 2004) at 561-63 (Barnett Decl. Ex. 2).

[4] Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, dated Dec. 15, 2005, ¶¶ 19-20 (Fowler Decl. Ex. 86). References to the "Fowler Decl." refer to the Exhibits filed on March 15, 2006 in support of the Track 1 Defendants' Motion for Summary Judgment.

in which he assigned liability and calculated damages based on the assumption that AWP should have equaled ASP.[5]

- This Court has recognized that Hartman's theory rests on the assertion that AWP equals ASP as a matter of law in the Medicare context. *See In re Pharmaceutical Industry Average Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005) ("Under Medicare Part B, [Hartman] calculates the but-for spread as 0% because it is set by law.")

Plaintiffs now proffer a new construction of "AWP" that is equally flawed and legally unsustainable.[6] The new theory is that, as a matter of statutory and regulatory interpretation, Congress and HCFA intended that AWP be "*rationally* linked to actual costs," "within *some reasonable zone* of actual averages," where it "could diverge from ASP (and hence EAC) to a *minimally reasonable magnitude*." (Pls.' Opp'n at 5, 6, 9 (emphases added).)[7] In other words, Plaintiffs' new theory requires the 1991 regulatory term and the 1997 statutory term "average wholesale price" to mean a price that is within a range above, but not too much above, average acquisition costs.

Plaintiffs' construction of "AWP" has no support whatsoever in the canons of legislative and regulatory interpretation:

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[5] Supplemental Declaration of Raymond S. Hartman in Support to Plaintiffs' Claims of Liability and Calculation of Damages: Addendum, dated February 3, 2006, ¶ 2 (Fowler Decl. Ex. 87).

[6] This shift in Plaintiffs' theory demonstrates the weakness of Plaintiffs' argument and supports the granting of summary judgment. *See, e.g., Bogdahn v. Hamilton Standard*, 973 F. Supp. 52, 53-54 (D. Mass. 1997) (granting motion for summary judgment against Plaintiffs who, "[e]ven after the motions for summary judgment were filed . . . continued . . . [in] attempts to reframe the causes of action in the hope of latching onto something that would work.").

[7] Plaintiffs proffer this so-called definition of "AWP" in conjunction with a criticism of the Defendants for not having provided a definition of the term. (*Id.* at 5-8, 9.) Unlike Plaintiffs, Defendants have always been clear on what "AWP" is and is not. AWP is a reference price or benchmark used for price negotiations; it is not an average of actual prices. Professor Berndt and Plaintiffs' expert on class certification agree. (2/9/2005 Report of Independent Expert Prof. Ernst R. Berndt ("Berndt Report") ¶ 16; 9/2/2004 Decl. of Stephen W. Schondelmeyer Supp. Pls.' Mot. for Class Certification ¶ 79).

- There is nothing in the language of the 1991 HCFA regulation or the 1997 Medicare statute that links AWP to acquisition costs.[8] To the contrary, the term HCFA and Congress used, "AWP," was a term of art in the pharmaceutical industry that HCFA and Congress had known for several years prior to 1991 was not a signal of provider acquisition costs. (*See* Mem. in Supp. of Track 1 Defs.' Mot. for Summ. J. at 2-14; Mem. in Opp'n to Pls.' Mot. for Summ. J. at 5-8.)

- There are no statements by HCFA or by Congress in the deliberations leading to or accompanying promulgation of either of these authorities – the 1991 HCFA regulation or the 1997 Medicare statute – that express a misunderstanding by either of these deliberative bodies that AWP was an indicator of provider acquisition costs. To the contrary, both HCFA and Congress were aware when they elected to use "AWP" that the term did not signal actual acquisition costs or an average thereof.[9] (*Id.*)

Plaintiffs make three points in support of their new construction of "AWP": (a) a flawed appeal to "plain meaning"; (b) reliance upon an edited portion of a 2002 statement from Thomas Scully, a former Administrator of CMS, which, taken as a whole, supports the Defendants', not Plaintiffs', position; and (c) misuse of a report published by the Office of Inspector General for the Department of Health and Human Services ("HHS-

[8] Plaintiffs' implicit suggestion that the mere appearance of "Estimated Acquisition Cost" ("EAC") in the 1991 HCFA Regulation means that AWP was supposed to be "reasonably linked" to EAC is entirely unsupported by the plain language of the regulation. (*See* Mem. Supp. Track 1 Defs. Joint Mot. Summ. J. at 10.)

[9] The legislative and administrative history offered in support of Defendants' motion demonstrates that HCFA and Congress understood that AWP was not reliably linked to ASP. (*See* Track 1 Defs.' 56.1 Stmt. ¶¶ 1 (quoting 1969 report stating that "list price has *little if any relationship* to the actual acquisition cost"), 3 (quoting 1975 report that AWP "often are *not closely related* to the drug prices actually charged to, and paid by providers"), 6 (quoting 1984 OIG Report stating that "pharmacies purchase drugs at prices that are *discounted significantly* below AWP or list price"), 16 (quoting government statement that "AWP *significantly overstates* the prices generally paid by providers"), 28 (quoting 1992 OIG report stating "AWP is *not a reliable indicator* of the cost of a drug to physicians") (emphases added).) Significantly, Plaintiffs do not dispute the extensive legislative and administrative history submitted by Defendants in support of their motion for summary judgment, as demonstrated by the chart attached hereto as Appendix A.

OIG") in 2003 purporting to provide "guidance", which are not indicative of Congressional or CMS intent.[10] (*See* Defs.' Opp'n to Pls.' Mot. for Summ. J. at 6-7.)

A. Plaintiffs' Reliance on the "Plain Meaning" of AWP is Misplaced

Plaintiffs continue to suggest that the words "average wholesale price" must be interpreted in accordance with their "natural, ordinary and familiar meaning." (Pls.' Opp'n at 5-6.) But they themselves have abandoned a plain meaning construction. Plaintiffs' construction of "AWP" – i.e., a number "within some reasonable zone of actual averages" – has no basis in the words, the grammar or the syntax of the term. Where as here, the words in question form a term of art known by HCFA and Congress, such term must be "interpreted by reference to the trade or industry to which they apply." *Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 371-72 (1986). Knowledgeable participants in the health care industry, including in particular HCFA, had known for years before 1991 that AWP did not signal acquisition costs and there were substantial and variable spreads between actual costs and AWPs. (*See* Defs.' Mem. in Supp. of Summ. J. at 2-4.)

[10] Plaintiffs also suggest that a 1975 Federal Register report and a 1980 Comptroller General report support their construction of AWP. (Pls.' Opp'n at 6.) Neither source suggests that *HCFA* or *Congress* believed or intended AWP to be "reasonably linked" to actual prices. Indeed, to the contrary, the very Federal Register report on which Plaintiffs' rely contains the following statement that Plaintiffs omit: "The Secretary disagrees, however, that average wholesale price should be used as the basis for "actual acquisition cost" determinations. Average wholesale price is not currently determined by surveying drug marketing transactions (i.e., by determining the actual price a pharmacist pays to a manufacturer or wholesaler for a particular drug product), and thus published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers." 40 Fed. Reg. at 32293 (July 31, 1975) (Fowler Decl. Ex. 3.) Furthermore, Plaintiffs' invocation of the 2003 House Committee on Ways and Means Report to support their position is entirely misplaced, given that the very same report also noted that "AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices." H.R. Rep. 108-178(II), 108th Cong. (July 15, 2003) at 197 (Fowler Decl. Ex. 82).

B. Statements of Thomas Scully Do Not Support Plaintiffs' Interpretation

As an initial matter, Mr. Scully, like Dr. Hartman, is not a proper substitute for statutory construction. (Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J. at 8-9.) Moreover, Plaintiffs take Mr. Scully's words completely out of context to present Mr. Scully as opining that AWP was understood by HCFA to have been "the average price at which wholesalers sell drugs to their customers." (Pls.' Opp'n at 5-6; Pls.' Mem. in Supp. of Mot. for Summ. J. at 43-44.) That is a gross mischaracterization. Instead, Mr. Scully's statement makes clear that HCFA understood (prior to its adoption of the industry term "AWP") that the term did not signal acquisition costs, as had been repeatedly confirmed to him through OIG reports to the same effect.[11] (Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J. at 8-9.)

C. OIG Guidance is Not Indicative of Regulatory or Legislative Intent

As they do with Mr. Scully's comments, Plaintiffs distort this guidance. Plaintiffs quote portions of the OIG report that deal with Average Manufacturer's Price – which is periodically reported to CMS as part of the Medicaid system – as if they pertained to Average Wholesale Price. (*Id.* at 10-11.) Moreover, the OIG "guidance" cited by Plaintiffs is not indicative of legislative or regulatory intent in part because this

[11] For example, immediately following the statement Plaintiffs quote, Mr. Scully stated: "Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the Red Book, which is published by Medical Economics Company, Inc. However, manufacturers and wholesalers increasingly give physicians and providers competitive discounts that reduce the actual amount the physician or provider actually pays for the drugs. . . . These discounts are not reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the Red Book." (Decl. of Steve W. Berman in Supp. of Plaintiffs' Mem. for Partial Summ. J. Against All Track 1 Defs., Ex. B.)

"guidance" was issued years after the term "average wholesale price" was incorporated into the 1991 regulation and the 1997 statute.

D. Plaintiffs Otherwise Do Not Challenge Defendants' Statutory Interpretation Analysis

Other than attempting to rely on the irrelevant sources described above, Plaintiffs do not dispute the legal framework set out by Defendants in their motion papers.[12] In particular, Plaintiffs agree that deference is owed to HCFA's interpretation of its regulation (*see* Pls.' Opp'n at 6), as required by the *Seminole Rock* line of cases. *See Visiting Nurse Ass'n of North Shore, Inc. v. Bullen*, 93 F.3d 997, 1002 (1st Cir. 1996). Because there is no indication that HCFA – and subsequently Congress – understood or intended AWP to be mean what Plaintiffs now ask this Court to adopt as the meaning, Plaintiffs' theory of liability collapses.

II. PLAINTIFFS CANNOT ESTABLISH CAUSATION.

Defendants' argument that Plaintiffs cannot establish causation in connection with their claims is based on two key facts: (1) the government was on notice that "AWP is not a reliable indicator of the cost of a drug to physicians,"[13] and (2) the government understood that "Medicare reimbursement . . . in many cases provided profit margins of

[12] *See also* AstraZeneca Pharmaceuticals LP's Individual Memorandum of Law in Opposition to Plaintiffs' Motion for Partial Summary Judgment on the Class 1 and Class 2 Claims Under Massachusetts Gen. Laws Ch. 93A.

[13] *See supra* at n.9; *see also* HHS-OIG Report, Physicians' Costs of Chemotherapy Drugs, A-02-91-01049, at. 2, 5, 11 (Nov. 6, 1992) (56.1 Stmt. ¶ 29; Fowler Decl. Ex. 26). Other documents make clear that HCFA understood this prior to 1992, and Congress understood this both before and after it adopted the Balanced Budge Act in 1997. (Fowler Decl. Exs. 1, 5, 8, 9, 13, 40, 42, 47, 58.)

more than 500% and, in some instances, more than 1000%."[14] Plaintiffs do not address or dispute these historical facts. Rather, they merely attempt to avoid these government statements by stating that "the documents relied upon by Defendants do no more than suggest that the government was aware that the acquisition costs on *some* drugs were *sometimes* below AWP." (Pls.' Opp'n at 10.)

It is not Defendants' burden to prove what the government knew. *See, e.g.*, *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) ("[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."). It is Plaintiffs' burden to prove that the government was deceived. They have failed to carry that burden here.

Plaintiffs attempt to dismiss that the government statements relied upon by Defendants on the ground that they "were authored by lower-government employees who did not have policy authority." (Pls.' Opp'n at 11.)[15] Plaintiffs fail to explain why they can rely on OIG statements and Congressional reports (*id.* at 6-7), but Defendants cannot – especially where, for purposes of their causation argument, Defendants are simply

[14] Z. Bentley and T. Jones to B. Vladeck, Oct. 2, 1996, at 1 (produced by the government as HHC 003-0479) (56.1 St. ¶ 42; Fowler Decl. Ex. 39). *See also* Report of the Committee on the Budget of the House of Representatives, at 1354 (June 24, 1997) (56.1 Stmt. ¶45; Fowler Decl. Ex. 42) ("Medicare reimbursement for the top 10 oncology drugs ranges from 20% to nearly 1000% per dosage more than acquisition costs.")

[15] Plaintiffs also contend that the documents "in many instances pertained to drugs dispensed from pharmacies." (Pls.' Opp'n at 11.) Plaintiffs' expert, Dr. Hartman, has taken the position that expectations with respect to physician-administered drugs can be informed by information with respect to self-administered drugs, Berman Decl. Exh. 1, Table 3, and HCFA has relied on information concerning pharmacy prices in setting policy for physician-administered drugs. (Fowler Decl. Ex. 19 at 25, 80.)

showing by the government's own words that the government was on notice of certain facts, which Plaintiffs cannot legitimately dispute. Nor do Plaintiffs explain why the statements of Thomas Scully, the Administrator of HCFA, are entitled to deference, but information received by his predecessor[16] and statements by his successors and superiors[17] are not.

Plaintiffs mischaracterize a number of OIG reports concerning spreads for pharmacy-dispensed drugs as the "primary OIG reports cited by Defendants." (Pls.' Opp'n at 11). Those reports are *not* the primary reports cited by Defendants, and they *also* refer to discounts for generic drugs as large as 41.78% (which translates to a mark-up of 72% over acquisition cost).[18] Plaintiffs also state that "the few studies that focus on physician-administered drugs" found spreads within Dr. Hartman's 30% liability yardstick (*id.* at 12); but the very same studies *also* found mark-ups over acquisition cost of 400% to 1000%.[19]

Unable to refute the government reports that Defendants in fact rely upon, Plaintiffs fall back on Dr. Hartman's opinion that the documents "about spreads on physician administered drugs over much of the damage period suggested that those spreads were not excessive." (Pls.' Opp'n at 12.) But Dr. Hartman has admitted that he

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[16] Fowler Decl. Ex 39.

[17] Fowler Decl. Exs 40, 47, 48, 58, 62, 68.

[18] Fowler Decl. Ex. 5 at 9.

[19] Fowler Decl. Ex. 26 at App. III; Fowler Decl. Ex. 46 at 8. In addition, Plaintiffs cite several documents that allegedly contain "conflicting conclusions" (*id.*), without bothering to mention that Defendants do not even cite those documents in their brief. Fowler Decl. Ex. 4; Fowler Decl. Ex. 41. These and other documents were included in Defendants' submission in order to complete the picture.

is not an expert on Medicare regulation;[20] he does not purport to be an expert on reading documents; and his "opinion" cannot create a genuine issue of material fact with respect to what the government said. *See, e.g.*, *Hayes v. Douglas Dynamics, Inc.*, 8 F.3d 88, 92 (1st Cir. 1993); *Johnson v. Brown & Williamson Tobacco Corp.*, 345 F. Supp. 2d 16, 20-21 (D. Mass. 2004). Dr. Hartman's opinions on this subject are inadmissible and worthless.[21]

In an effort to create an issue of fact, Plaintiffs suggest – without citing to any authority other than Dr. Hartman – that the government was not aware of the "spreads" on various drugs. (Pls.' Opp'n at 14-15.)[22] The materials demonstrate, however, that the government was aware at various times of the spreads of numerous drugs at issue in this case, including Zoladex, Vepesid, Cytoxan, Albuterol and Remicade.[23] More to the

[20] Hartman Dep. Tr. (Feb. 27, 2006) at 879-82 (Barnett Decl. Ex. 3).

[21] Plaintiffs allege that Dr. Hartman's liability report creates an issue of fact with respect to causation because Defendants have not moved to strike it. (Pl. Opp. at 30.) An expert report cannot create facts where none exist. *Merit Motors, Inc. v. Chrysler Corp.*, 569 F.2d 666 (D.C. Cir. 1977). In any event, if the Court is inclined to consider Dr. Hartman's report, Defendants proffer the reports of their experts, which demonstrate that Dr. Hartman's report is inaccurate, unreliable and unscientific.

[22] Plaintiffs blatantly mischaracterize the basis for certain manufacturers' settlements with the federal government as proof that the government did not condone the existence of spreads. (Pls.' Opp'n at 19-21.) In fact, these settlements have nothing to do with Plaintiffs' claims of AWP inflation, and, in the case of TAP and AstraZeneca, related to an agreement to plead guilty to a violation of the Prescription Drug Marketing Act (PDMA) involving the distribution of samples. Plaintiffs' Complaint does not—and could not—allege a claim based on the PDMA, s*ee* 21 U.S.C. § 337(a); *see also Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995) (no private right under Food, Drug, and Cosmetic Act of which PDMA is a part), and these settlements provide no evidence that the government believed AWPs were reasonably related to providers' acquisition costs.

[23] *See* Barnett Decl. Ex. 4 at 7 (Zoladex: 89% in 1998 report); Barnett Decl. Ex. 4 at 6 (Zoladex: 107% in 2001 report); Fowler Decl. Ex. 39 (Vepesid: 700% in 1996 letter); Fowler Decl. Ex. 26 (Cytoxan: 143% in 1992 report); Fowler Decl. Ex. 35 (Albuterol: 231% in 1996 report), Fowler Decl. Ex. 46 (Albuterol: 180% in 1997 report), Fowler Decl. Ex. 55 (Albuterol: 550% in 1998 report), Fowler Decl. Ex. 63 (Albuterol: 571% in 2000 report), Fowler Decl. Ex. 72 (Albuterol: 567% in 2001); *see also* Decl. of Sumanth Addanki, Ex. 3A-B (summarizing spreads for albuterol reported in public documents). Spreads

point, Plaintiffs cannot prove that the government did *not* have access to the acquisition cost of any drug for which it wanted information. Furthermore, even though the government had spread information for many drugs, it did not change the reimbursement amounts. Therefore, Plaintiffs cannot prove that knowledge of spreads would have had any impact on what they paid.[24]

Relying on Judge Stearns' opinion in *In re Lupron Mktg. & Sales Practices Litig.*, 295 F.Supp.2d 148, 163 (D. Mass. 2003), Plaintiffs contend that "[a]t least one other Court has rejected Defendants' 'everyone knew' defense." (Pls.' Opp'n at 22.) The linchpin of Judge Stearns' opinion, however, was that there was no way of knowing, on a motion to dismiss, whether the government was aware of the mark-up for Lupron. *Id.* at 168n. 19. Here, it is undisputed that the government knew about "megaspreads." As Judge Stearns later commented in approving the *Lupron* settlement, "Defendants have a powerful argument that the AWP was known to Congress and large insurers to be an artificial benchmark with no real market significance." 228 F.R.D. 75, 97 (D. Mass. 2005).[25]

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for Johnson & Johnson's drug Remicade were published and therefore publicly available. *See* Johnson & Johnson's Memorandum in Support of Motion for Summary Judgment.

[24] Plaintiffs next suggest that, even if the government knew about "megaspreads," it was unable to "move quickly." (Pls.' Opp'n at 16.) Plaintiffs do not cite anything to support their analysis. In any event, their assertion is beside the point. Regardless of whether the government could move quickly, it could not have been deceived if it knew the truth. Plaintiffs' additional assertion, that the government didn't know about Defendants' alleged "manipulation" even if it did know about spreads, (Pls.' Opp'n at 13), is a red herring. Knowledge of the spreads alone is sufficient to break the causal chain.

[25] Plaintiffs citation to *Pappas v. Pella Corp.*, No. 1-05-1702, 2006 Ill. App. LEXIS 272 (1st Dist. Feb. 21, 2006) is beside the point. (Pls.' Opp'n at 32.) Defendants are not arguing for a heightened demonstration of causation. They are arguing that someone in the chain of causation must be deceived.

Plaintiffs next concede that they must prove causation, but argue that causation has been established here because: "Had Defendants not engaged in manipulation of spreads, Medicare reimbursement and co-pays based thereon would have been lower." Pls.' Opp'n at 29. But there was nothing Defendants could have done to cause Plaintiffs to act differently. As Plaintiffs concede, *see* Pl. Mem. in Support of Partial Summ. J. at 124, the terms of Plaintiffs' transactions were set by Medicare. Plaintiffs cannot distinguish the cases cited by Defendants which hold that, where a plaintiff claims to have suffered injury as a result of deception by a third party, the plaintiff must demonstrate that the third party was actually deceived. *See,* e.g., *Shannon v. Boise Cascade Corp.*, 208 Ill. 2d 517, 525-26, 805 N.E.2d 213, 218 (2004) ("In those circumstances, the purchaser, who may have no independent knowledge . . . is deceived because of the deception of the [third party] who reasonably should have had correct knowledge.").[26]

The law under Mass. G.L. ch. 93A is clear: a person cannot be deceived if that person knows what is alleged to be misleading. *See,* e.g., *Brazas Sporting Arms, Inc. v. Am. Empire Surplus Lines Inc., Co.*, 220 F.3d 1, 9 (1st Cir. 2000).[27] Since it is

[26] Plaintiffs rely on *Lupron* for the proposition that they can establish causation so long as their injury was foreseeable. (Pls.' Opp'n at 30-31.) The court in *Lupron*, however, did not hold that the Plaintiffs did not have to prove that the government was deceived. The entire premise of the *Lupron* decision was that Plaintiffs had alleged that the government was deceived. 295 F. Supp. 2d at 168 n. 19. Here Defendants have shown that the government was not deceived and Plaintiffs have failed to rebut that showing.

[27] *See also Ahern v. Scholz*, 85 F.3d 774, 798 (1st Cir. 1996) (court should consider "what both parties knew or should have known" when assessing whether a challenged act is unfair under ch. 93A); *Tagliente v. Himmer*, 949 F.2d 1, 7-8, (1st Cir. 1991) (purchaser knew the alleged defect); *Mass. Farm Bureau Fed., Inc. v. Blue Cross of Mass., Inc.*, 403 Mass. 722, 731, 532 N.E.2d 660, 665 (1989) (insurer understood transaction); *USM Corp. v. Arthur D. Little Sys., Inc.*, 546 N.E.2d 888, 898 (Mass. Ct. App. 1989) (plaintiff "was not misled by any of [defendant's] financial reports."); *Madan v. Royal Indem. Co.*,

undisputed that the government understood that "AWP is not a reliable indicator of the cost of a drug to physicians," and it knew that "Medicare reimbursement . . . in many cases provide[s] profit margins of more than 500% and, in some instances, more than 1000%," Plaintiffs cannot prove that the government was deceived and, consequently, cannot establish any causal connection between Defendants' conduct and Plaintiffs' alleged loss as a matter of law.

III. PLAINTIFFS' CLASS 2 CLAIMS ARE BARRED BY THE STATUTE OF LIMITATIONS

Plaintiffs ignore the requirement of Massachusetts law that a plaintiff with knowledge of facts suggesting injury must demonstrate reasonable diligence in the pursuit of claims. *Tagliente v. Himmer*, 949 F.2d 1, 5 (1st Cir. 1991). Plaintiffs have made no such showing of diligence; their claims, therefore, are barred.

Plaintiffs dispute that BCBS of Massachusetts and other Massachusetts payors' knowledge of the actual discounted prices (far below AWP) at which physician-administered drugs were available started the running of the statute, claiming that such information "was never available to the non-staff-model HMO lines of business, including the Medi-Gap side." (Pls' Opp'n. at 35.) Even if Plaintiffs' were correct, BCBS's knowledge cannot be bifurcated. The law is clear that the knowledge of all BCBS employees is imputed to the corporation, wherever those employees work. *See United States v. Bank of New England*, 821 F.2d 844, 856 (1st Cir. 1987). As the First Circuit said in *Bank of New England*:

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532 N.E.2d 1214, 1218 (Mass. App. Ct. 1989) (a plaintiff's knowledge and what he reasonably should have known may be factors in determining whether an act or practice is unfair); *Dinjian v. Dinjian*, 495 N.E.2d 882 (Mass. App. Ct. 1986) (Plaintiffs understood that Defendants had a financial interest in a loan).

> "[T]he knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation. [Citation omitted.] Corporations compartmentalize knowledge, subdividing the elements of specific duties and operations into smaller components. The aggregate of those components constitutes the corporation's knowledge of a particular operation. It is irrelevant whether employees administering one component of an operation know the specific activities of employees administering another aspect of the operation."

Id.[28]

Plaintiffs also argue that they were not on notice of the large spreads at issue here. That contention – and Plaintiffs' argument that they understood AWPs to be close to ASPs – is belied by the undisputed fact that Plaintiffs were purchasing the very drugs at issue here at spreads up to and exceeding 1,000%. The declaration of Eric Gaier dated March 15, 2006 filed with Defendants' summary judgment motion collected data regarding Massachusetts payors' (including BCBS of Massachusetts) purchases of physician-administered drugs from Track 1 Defendants in the early and mid-1990s. Those purchases were at varying prices well below AWP and reflected spreads of up to 2,200%. (*See* Barnett Decl. Ex. 6.)

Plaintiffs with knowledge of facts suggesting they have been injured have an affirmative duty of due diligence to investigate and discover their claims, and the burden is on Plaintiffs to establish they could not have discovered their claims within the period

[28] *Accord, Sarna v. American Bosch Magneto Corp.*, 290 Mass. 340, 344, 195 N.E. 328, 330 (1935) ("The defendant is chargeable with the combined knowledge which all its agents acquired within the scope of their authority together with legitimate inferences from all the evidence"); *Paloeian v. Day*, 299 Mass. 586, 591, 13 N.E.2d 398, 401 (1938) (same); *Sunrise Properties v. Bacon, Wilson, Ratner, Cohen, Salvage, Fialky & Fitzgerald, P.C.*, 425 Mass. 63, 68, 679 N.E.2d 540, 543-44 (Mass. 1997) (Citing *Bank of New England* and holding law firm president's knowledge of insurance claim was imputed to firm even though he did not inform other members of firm); *New England Trust Co. v. Bright*, 274 Mass. 407, 411-15, 174 N.E. 469, 470-71 (1931) (Employee's knowledge of improper conduct was imputed to defendant employer and barred recovery from plaintiff); *DeVaux v. American Home Assurance Co.*, 387 Mass. 814, 818, 444 N.E.2d 355, 358 (1983) ("When an agent acquires knowledge in the scope of her employment, the principal, here the attorney, is held to have constructive knowledge of that information").

provided by the applicable statute of limitations. *Tagliente*, 949 F.2d at 5 ("The burden is on the plaintiff to prove that in the exercise of reasonable diligence she could not have known of the misrepresentation within the statute of limitations."); *Maggio v. Gerard Freezer & Ice, Co.*, 824 F.2d 123, 130 (1st Cir. 1987) (if plaintiff had "exercised a reasonable degree of diligence" he would have discovered his claim prior to the statute running.).[29] Plaintiffs have made no showing whatsoever that they acted diligently.

Plaintiffs also claim that the statute has been tolled by Defendants' alleged fraudulent concealment. Even if the court were to assume – contrary to fact – that Defendants had committed acts of concealment that were fraudulent,[30] for the statute to be tolled under Mass. Gen. Laws. Ann. ch. 260, § 12, Defendants' conduct must have prevented Plaintiff from discovering the cause of action. *Wise v. Hubbard*, 769 F.2d 1, 3-4 (1st Cir. 1985); *Maggio*, 824 F.2d at 130. The estoppel provision of ch. 260 § 12 "is generally not available where the plaintiff is capable of discovering the facts allegedly concealed." *Wise*, 769 F.2d at 4 (*quoting Burbridge v. Board of Assessment of Lexington*, 11 Mass. App. Ct. 546, 549-50, 417 N.E.2d 477, 480 (1981)). Here, Plaintiffs clearly were capable of discovering the facts, in fact, they knew, and therefore their claims are barred prior to October 1997.

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[29] *See also Friedman*, 371 Mass. at 486-87, 358 N.E.2d at 997-98; *Salois v. Dime Sav. Bank of New York*, No. Civ. A. 95-11967-PBS, 1996 WL 33370626, at *8 (D. Mass. Nov. 13, 1996), *aff'd*, 128 F.3d 20 (1st Cir. 1997); *Albrecht v. Clifford*, 436 Mass. 706, 715, 767 N.E.2d 42, 49-50 (Mass. 2002).

[30] The acts on which Plaintiffs rely consist primarily of Defendants keeping their prices to customers confidential, a normal business practice. Similarly, the government advocacy of which Plaintiffs complain cannot, as a matter of law, constitute fraudulent concealment. *See Estate of Sarocco v. Gen. Elec. Co.*, 939 F. Supp. 91, 97 (D. Mass. 1996).

Finally, Plaintiffs' claim that whether Plaintiffs' knowledge was sufficient to trigger the statute is "with rare exception, a jury issue." (Pls.' Opp'n at 34 (*quoting In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 183-84 (D. Mass. 2003).[31]) Not so: there are numerous cases in this Court, the First Circuit and the Massachusetts courts where summary judgment on the statute of limitations has been granted in 93A cases. *Maggio*, 824 F.2d at 131; *Salois*, 1996 WL 33370626, at *11; *Hanson Hous. Auth. v. Dryvit System, Inc.*, 29 Mass. App. Ct. 440, 448, 560 N.E.2d 1290, 1295 (1990); *Bowen v. Eli Lilly & Co., Inc.*, 408 Mass. 204, 211, 557 N.E.2d 739, 743 (1990); *Whitcomb v. Pension Dev. Co., Inc.*, 808 F.2d 167, 172-73 (1st Cir. 1986); *Albrecht*, 436 Mass, 715, 716, 767 N.E.2d at 50; *Keane Inc. v. Swenson*, 81 F. Supp. 2d 250 (D. Mass. 2000).[32]

CONCLUSION

For all of the foregoing reasons, the Track 1 Defendants' Joint Motion for Summary Judgment should be GRANTED.

Respectfully submitted,

THE FOLLOWING TRACK 1 DEFENDANTS

By:____/s/ Jessica V. Barnett_____

[31] Plaintiffs' reliance on the *Lupron* motion to dismiss decision is particularly ironic here. In that case, after years of discovery, the court noted that third-party payors "were the most likely to have been aware of the manipulation of AWP by TAP and therefore the most vulnerable to TAP's knowledge defense." *Lupron*, 228 F. R.D. 75, 97 (D. Mass. 2005).

[32] Because there is no genuine issue of fact concerning whether BCBS Massachusetts had knowledge of the spreads and therefore the means to discover its claims, there is no material conflict in the expert testimony on this issue, as Plaintiffs' incorrectly assert (Opp. Br. at 36), and summary judgment is appropriate.

Nicholas C. Theodorou (BBO # 496730)
Jessica V. Barnett, Esq. (BBO# 650535)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110

D. Scott Wise
Michael Flynn
Kimberley Harris
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

Attorneys for AstraZeneca Pharmaceuticals LP

Steven M. Edwards
Lyndon M. Tretter
Hogan & Hartson, LLP
875 Third Avenue, Suite 2600
New York, NY 10022

Attorneys for the Bristol-Myers Squibb Co. and Oncology Therapeutics Network Corp.

William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
Patterson, Belknap, Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036-6710

Attorneys for the Johnson & Johnson Defendants

John T. Montgomery (BBO #352220)
Steven A. Kaufman (BBO #262230)
Eric P. Christofferson (BBO #654087)
Ropes & Gray LLP
One International Place
Boston, MA 02110

Attorneys for Schering-Plough Corp. and Warrick Pharmaceuticals Corp.

Dated: April 28, 2006

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was served on all counsel of record via Lexis/Nexis File & Serve on April 28, 2006.

___/s/ Jessica V. Barnett_____
Jessica V. Barnett